UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

GEMINI INSURANCE COMPANY,
a foreign corporation,

Plaintiff,

vs.

CASE NO:

USPLABS, LLC,
a Texas limited liability company,

Defendant.
_____/

COMPLAINT FOR DECLARATORY RELIEF

GEMINI INSURANCE COMPANY ("Gemini") files suit against USPLABS, LLC ("USP"), and alleges:

NATURE OF ACTION

1. This is an action for declaratory relief under 28 U.S.C. § 2201 for a determination that there is no insurance coverage available for lawsuits involving USP's products containing DMAA, which were never approved for sale by the FDA and were, in fact, detained by the FDA and eventually destroyed, among other reasons addressed below.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 28 U.S.C. § 1332 because there is diversity of citizenship and the amount in controversy exceeds $75,000, exclusive of interest and costs.

3. Venue is proper in this Court under 28 U.S.C. § 1391 because USP's principal place of business is in this district and the subject insurance policy was issued in this district.

4. All conditions precedent have occurred, been performed, or have been waived.

THE PARTIES

5. Gemini is a Delaware corporation with its principal place of business in Connecticut. For this action, Gemini issued a surplus lines, excess liability insurance policy to USP.

6. USP is a Texas limited liability company with its principal place of business in Dallas, Texas. For this action, USP manufactured and distributed dietary supplements containing the ingredient DMAA under the trademarks "Jack3d" and "OxyElite" (together, "DMAA Products").

COMMON ALLEGATIONS

7. ***THE DMAA LAWSUITS***. USP has been sued in various lawsuits across the country alleging injuries caused by ingestion of USP's unapproved DMAA Products ("DMAA Lawsuits").

8. A list of the pending DMAA Lawsuits is attached as Exhibit "A."

9. The DMAA Lawsuits allege, among other claims, that "despite FDA's warning that the [DMAA Products] [were] illegal and posed material safety risks," USP continued to sell its DMAA Products without regard for the safety of consumers. (Exhibit B-1, ¶324-328.)[1]

10. ***USP'S SALE OF DMAA PRODUCTS***. USP registered the trademark "OxyElite Pro" in 2009 and "Jack3d" in 2010.

11. The DMAA Products were marketed as weight loss and muscle-building supplements, respectively, and were available for purchase in retail stores those same years.

[1] Because of the large number of complaints, Gemini has attached a representative complaint as Exhibit B-1. Gemini will file a separate Notice of Filing Exhibits for the remaining pending complaints, which will be labeled B-2 through B-7.

12. One plaintiff alleged that he purchased OxyElite "in or about 2009" from a GNC store in Maryland. (*Id*., ¶127.)

13. Another plaintiff alleged that he purchased Jack3d "in or about March 2010" from a Vitamin Shoppe store in Pennsylvania. (*Id*., ¶97.)

14. ***DMAA LINKED TO SERIOUS ILLNESS***. The DMAA Products contain the ingredient 1,3-dimethylamylamine (DMAA), also known as methylhexanamine or geranium extract, which is an amphetamine derivative.

15. As of April 11, 2013, the FDA had received 86 reports of illnesses and death associated with supplements containing DMAA.

16. The FDA repeatedly declared that the DMAA Products were unsafe, including in a public warning issued on April 11, 2013 calling DMAA a dangerous stimulant and advising consumers to avoid consuming any products containing the ingredient. (Exhibit C.)

17. The FDA specifically warned that ingestion of DMAA elevates blood pressure and can lead to cardiovascular problems, including heart attacks.

18. According to one plaintiff, he ingested DMAA Products from October 2011 through November 2011 and, on November 4, 2011, "suffered an aortic dissection and related injuries." (Exhibit B-1, ¶47-49.)

19. Another plaintiff alleged that he ingested DMAA Products from October 2011 until December 2011 and, specifically on December 26, 2011, "suffered myocardial infarction and related injuries." (*Id*., ¶92-95.)

20. On April 16, 2013, USP announced its plan to reformulate the DMAA products without DMAA; however, USP refused to destroy it inventory of DMAA Products and continued to distribute the DMAA Products.

21. ***DMAA PRODUCTS UNAPPROVED***. A "dietary supplement" is a product that contains a "dietary ingredient" intended to supplement the human diet, such as vitamins, minerals, herbs or other botanicals, and amino acids.

22. The FDA notified USP that the DMAA Products were adulterated and therefore illegal to sell because DMAA is not a "dietary ingredient." In an April 18, 2013 letter to USP, the FDA explained:

> a. DMAA does not qualify as a dietary ingredient under § 201(ff)(1)(C) or 201(ff)(1)(F) of the Federal Food, Drug, and Cosmetic Act because DMAA is not an herb or other botanical, nor is it a constituent of a botanical.
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> b. DMAA does not qualify as a dietary ingredient under § 201(ff)(1)(E) because there is no evidence that DMAA is a dietary substance for use by man to supplement the diet by increasing total dietary intake.
>
> c. Because DMAA does not qualify as a dietary ingredient, the DMAA Products are adulterated under § 402(a)(2)(C) of the Act.
>
> d. The introduction or delivery for introduction into interstate commerce of any food that is adulterated is a prohibited act under § 301(a) of the Act (21 U.S.C. 331(a)). Further, it is a prohibited act under § 301(ll) of the Act (21 U.S.C. 331(ll)) to introduce or deliver for introduction into interstate commerce any food to which a drug approved under § 505 of the Act (21 U.S.C. 355) has been added, unless the added drug was marketed in food before being approved under § 505. DMAA was approved as a drug in 1948 under § 505 of the Act and, to the best of FDA's knowledge, was not marketed in food prior to such approval, either on its own or based on its alleged presence as a component of *P. graveolen*. In the absence of such evidence, the DMAA Products are in violation of § 301(ll) of the Act.

(Exhibit D.)

23. The FDA further notified USP that, even if DMAA was a "dietary ingredient," the DMAA Products were nevertheless "adulterated" because DMAA was a "new dietary ingredient" (NDI) for which USP was required by law to submit a premarket safety notification

(also known as a New Dietary Ingredient Notification or "NDIN") to the FDA at least 75 days prior to marketing the DMAA Products.

24. USP failed to provide the required premarket safety notification to the FDA before it began marketing the DMAA Products.

25. Based on these regulatory violations, the FDA required USP to immediately cease distribution of the DMAA Products or face enforcement action.

26. Despite the warnings from the FDA, USP continued to distribute the DMAA Products.

27. ***FDA INVOKES DETENTION AUTHORITY***. Due to USP's refusal to cease distribution of the DMAA Products, the FDA invoked its administrative detention authority under the FDA Food Safety Modernization Act (FSMA), which authorizes the FDA to detain adulterated food for up to 30 days.[2]

28. On July 2, 2013, before the thirty day detention period expired, USP capitulated and agreed to destroy its remaining stock of the DMAA Products valued at approximately $8 million under the supervision of the FDA.[3]

29. ***FEDERAL SEIZURE ACTIONS***. The FDA also intervened to detain the DMAA Products stored in General Nutrition Corporation (GNC) warehouses across the country.

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[2] The FDA has used its detention powers sparingly. Since 2011, there have been only two public detentions, other than USP's DMAA Products, including one for food contaminated with rodent droppings and another involving an incident where listeria monocytogenes was discovered on processing equipment for cold-smoked salmon.

[3] On May 23, 2013, after USP indicated it would continue to sell the remaining stock of DMAA Products, the Texas Department of State Health Services placed an embargo on the DMAA Products.

30. In June 2013, the United States Department of Justice, on behalf of the FDA, filed complaints in three federal courts requesting orders to permit seizure and condemnation of the DMAA Products located in the GNC warehouses.

31. Finding "probable cause" that the DMAA Products were adulterated, the courts authorized the seizure of the DMAA Products.

32. Under threat of imminent seizure, GNC agreed to destroy its entire remaining inventory of the DMAA Products in its warehouses under the FDA' supervision.

33. ***GEMINI (FOLLOW FORM) EXCESS POLICY***. Gemini issued a claims-made and reported excess liability policy to "USPLabs, LLC," as the Named Insured, for the period effective from 03/26/2013 through 03/26/2014, and bearing Policy No. EX_11794-1. (Exhibit E.)

34. As a condition precedent to coverage under the Gemini Policy, USP must satisfy the $250,000 Per Claim self-insured retention (SIR) under the Gemini excess policy and the $250,000 Per Claim SIR under controlling underling insurance.

35. ***CONTROLLING UNDERLYING INSURANCE***. Gemini's excess policy follows form to "controlling underlying insurance," which here is a claim-made and reported liability policy issued by Underwriters at Lloyd's, London, Syndicate No. 1084 ("Lloyd's") to USP for the same policy period and subject to a $250,000 Per Claim SIR for DMAA-related claims. (Exhibit F.)[4]

36. In pertinent part, the Policy contains these pertinent provisions:

[4] Because Gemini's excess policy follows form to the Lloyd's policy (except where the excess policy is more restrictive), for purposes of this lawsuit, both policies are collectively referred to in the singular as the "Policy."

SECTION I – COVERAGES

COVERAGE A BODILY INJURY AND PROPERTY DAMAGE LIABILITY

1. Insuring Agreement

We will pay those sums that **you** become legally obligated to pay in excess of the self-insured retention as **damages** for **bodily injury** or **property damage** to which this insurance applies. **We** will have the right and duty to defend any **suit** seeking those **damages** to which this insurance applies. However, **we** will have no duty to defend **you** or pay those sums that **you** become legally obligated to pay for **bodily injury** or **property damage** to which this insurance does not apply. ...

b. This insurance applies to **bodily injury** and **property damage** only if:

(1) The **bodily injury** or **property damage** is caused by an **occurrence** that first takes place in the **coverage territory**; and

(2) The **onset** of the **bodily injury** or **property damage** does not first take place before the Retroactive Date, if any, shown in the Declarations. All **property damage** or **bodily injury** caused by or related to an occurrence is deemed to first take place when the **property damage** or **bodily injury** first becomes known to anyone, regardless of whether the **damage** or injury is continuous, progressive, repeated, changing or results from exposure to substantially the same general harm; and

(3) The **claim** for **damages** is first made again **you** during the policy period. All **claims** for **damages** arising out of an **occurrence** will be deemed to have been made at the time the first of these **claims** is made against **you**; and

(4) A **claim** is reported to **us** by **you** in writing during the policy period or any Extended Reporting Period we provide under **EXTENDED REPORTING PERIOD** (Section VII). …

d. This insurance does not apply to and we shall have no obligation or duty to defend **you** for **damages** in respect to any **claim** or **onset** alleging **bodily injury** or **property damage**:

(1) which results from any work or operations performed by or on behalf of **you** prior to the retroactive date of the policy; and/or

(2) which results from any work or operations performed by or on behalf of **you** which work or operation has commences or is pending prior to the retroactive date of this policy, and/or …

(4) any other injury or damage of which you had knowledge or could have reasonably foreseen would arise prior to the retroactive date of this policy.

This applies whether or not:

(a) **Damages** continue or progress during the policy period; or

(b) Ultimate liability has been established; or

(c) The final amount of **damages**, loss, cost or expense has been established.

ENDORSEMENT

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY

PAST LIABILITIES EXCLUSION

IT IS AGREED SUCH COVERAGE AS IS AFFORDED BY THIS POLICY FOR ALL ACTIVITIES/OPERATIONS AND/OR PRODUCTS/COMPLETED OPERATIONS SHALL ONLY APPLY TO CLAIMS ARISING OUT OF ACTIVITIES/OPERATIONS AND/OR PRODUCTS MANUFACTURED AND/OR SOLD AND/OR PERFORMED BY ANY INSURED OR ADDITIONAL INSURED AFTER **03/26/13** AND/OR COMPLETED OPERATIONS COMPLETED AFTER **03/26/13**.

NO COVERAGE NOR DUTY TO DEFEND IS AFFORDED TO THE INSURED FOR ANY ACTS OF THE INSURED WHICH OCCURRED PRIOR TO THE DATE SHOWN ABOVE.

ENDORSEMENT

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY

SPECIFIED HERBAL PRODUCTS EXCLUSION

IT IS AGREED THERE IS NO COVERAGE AFFORDED UNDER THIS POLICY FOR THE FOLLOWING PRODUCT(S), DERIVATIVES OR RELATED BOTANICALS AND OR EXTRACTS WHETHER AS A PRIMARY INGREDIENT OR IN COMBINATION WITH OTHER INGREDIENTS: …

PENNYROYAL OIL STEPHANIA, OR ANY ADULTERATED BOTANICALS

FIRST EXPOSURE TO DMAA AND UNIDENTIFIED DMAA PRODUCT ENDORSEMENT

1. **SECTION I – EXCESS LIABILITY COVERAGE, 3., Exclusions,** is amended by the addition of the following:

   This insurance does not apply to any claim, loss, cost or expense based upon or arising the ingestion, contact with or exposure to **DMAA** where such ingestion, contact with or exposure first took place prior to the retroactive date.

2. Exception to Exclusion

This exclusion shall not apply if claimant first ingested, came into contact with or was exposed to a product containing **DMAA** provided that:

a. The product containing **DMAA** that claimant first ingested, came into contact with or was exposed to was sold to claimant with the **updated label**; and

b. The injury to claimant caused by the DMAA took place after the retroactive date but before the end of the policy period.

3. The following shall also apply:

a. In the event that:

- A "claim" is first made against the insured alleging in whole or in part ingestion, contact with or exposure to **DMAA**; and
- It is unclear or has not yet been determined whether the conditions to the Exception stated in Paragraph 2. above ("Exception Conditions") have been satisfied;

Then the Company shall have no duty to defend such "claim" or pay any expense including attorneys fees in the defense of such "claim". Any such expense including attorneys fees incurred in the defense of such "claim" shall not erode the self-insured retention or the "underlying limits".

b. Notwithstanding the foregoing, the Company has the right to participate in the defense of such "claim".

c. In the event that the "Exception Conditions" have been satisfied, then any expense incurred in the defense of such "claim" otherwise covered under this Policy, and any coved loss, would erode the self insured retention and the "underlying limits", and apply to this insurance if otherwise covered once the retention and "underlying limits" have been eroded, commencing on the date that the court determines, or we and you agree, the "Exception Condition" have been satisfied.

4. The following definitions apply to this Endorsement:

a. **Updated label** means all labels that the insured has agreed to use for any product containing **DMAA** pursuant to the Stipulation and Agreement of Settlement in Govinda Hogan v. USPlabs, LLC, Superior Court of the State of California, County of Los Angeles, Case No. BC 486925, dated July 10, 2012.

b. **DMAA** mean dimethylamylamine or any good or product containing such good or product, or containing a similar chemical formula of such good or product, or which is a derivative of any such good or product.

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY

EXCLUSION FOR UNAPPROVED GOODS OR PRODUCTS

SECTION I – EXCESS LIABILITY COVERAGE, Paragraph 3., Exclusions, is amended by the addition of the following:

This insurance does not apply to any claim, loss, cost or expense based upon or arising out of any goods or products distributed, handled, manufactured or sold by, or disposed of by, the insured or any person or organization acting on behalf of the insured:

a. If so distributed, handled, manufactured, sold or distributed:

- before such goods or products have been approved for such distribution, handling, manufacture, sale or disposal; or
- after such goods or products have been declared unsafe;

by the United States Food and Drug Administration (or appropriate governmental authority having jurisdiction over such distribution, handling, manufacturing, sale or disposal); or

b. If so distributed, handled, manufactured, sold or disposed of without first complying with all applicable regulatory requirements enforced by the United States Food and Drug Administration (or appropriate governmental authority having jurisdiction over such distribution, handling, manufacturing, sale or disposal) at the time such activity was performed.

COUNT I – NO COVERAGE FOR UNAPPROVED PRODUCTS

37. Gemini incorporates paragraphs 1 - 36.

38. The Policy's Unapproved Products Exclusion precludes coverage for any claim in any way arising out of any product distributed or sold by USP without first complying with all applicable regulatory requirements enforced by the FDA.

39. The exclusion further precludes coverage for claims arising out of products distributed or sold before the products have been approved for sale by the FDA or after the product have been declared unsafe by the FDA.

40. USP failed to comply with all the FDA regulatory requirements prior to distributing its DMAA Products, including but not limited to failing to submit the required premarket safety notification to the FDA for the DMAA Products.

41. USP never submitted a premarket safety notification to the FDA for the DMAA Products.

42. USP also never received approval from the FDA for the DMAA Products, which was required because the DMAA Products contained DMAA, which is not a "dietary ingredient."

43. Finally, USP distributed the DMAA Products after they were declared unsafe.

44. Because USP failed to comply with the FDA regulations prior to distributing its DMAA Products, failed to obtain approval for the DMAA Products, and distributed DMAA Products after they were declared unsafe, the Unapproved Products Exclusion applies and Gemini accordingly has no defense or indemnity obligation to USP.

COUNT II – NO COVERAGE FOR OPERATIONS PERFORMED OR PRODUCTS MANUFACTURED OR SOLD BEFORE 03/26/2013

45. Gemini incorporates paragraphs 1 - 36.

46. Under the Policy's insuring agreement, coverage does not apply to any claim alleging bodily injury resulting from work or operations performed (or commenced) by USP prior to the policy's Retroactive Date of 03/26/2013.

47. Similarly, under the Policy's Past Liability Exclusion, there is no coverage for claims arising out of products manufactured or sold prior to 03/26/2013 or operations performed by USP prior to 03/26/2013.

48. Even if the Unapproved Products Exclusion does not apply, under the DMAA Exclusion there is no coverage for any claim arising out of the ingestion, contact with,

or exposure to DMAA where such ingestion, contact with or exposure first took place prior to the Retroactive Date.

49. USP began selling DMAA Products in 2009 and 2010, which is three years before the Retroactive Date.

50. The DMAA Products were being researched, developed, designed, tested, manufactured, packaged, formulated, inspected, labeled, distributed, marketed, and promoted, prior to the Retroactive Date.

51. USP stopped production of the DMAA Products on April 16, 2013, which is less than one month after the Policy incepted.

52. All of the DMAA Products were destroyed by July 2013.

53. Accordingly, under the insuring agreement, Past Liability Exclusion, and DMAA Exclusion, Gemini has no defense or indemnity obligation to USP for injuries resulting from work or operations commenced before 03/26/13, products manufactured or sold prior to that date, or ingestion, contact with or exposure to DMAA prior to that date.

COUNT III – NO COVERAGE WHERE ONSET OF INJURY WAS BEFORE 03/26/2013

54. Gemini incorporates paragraphs 1 - 36.

55. Pursuant to the Policy's insuring agreement, no coverage exists if the "onset" of the bodily injury first takes place before the Retroactive Date.

56. The Policy defines "onset" as the date when the injury is first diagnosed or first discovered.

57. Accordingly, to the extent the onset of bodily injury alleged in the DMAA Lawsuits is prior to the Retroactive Date, Gemini has no defense or indemnity obligation to USP.

COUNT IV – NO COVERAGE FOR ANY CLAIM MADE OR REPORTED OUTSIDE THE POLICY PERIOD

58. Gemini incorporates paragraphs 1 - 36.

59. Under the insuring agreement, the Policy applies only to claims first made against USP during the policy period and reported to Gemini, in writing, during the policy period.

60. The insuring agreement further provides that "all claims for damages arising out of an occurrence will be deemed to have been made at the time the first of these claims is made against [USP]."

61. Accordingly, pursuant to the Policy's insuring agreement, Gemini has no defense or indemnity obligation to USP for any claim made against USP outside of the policy period or reported to Gemini outside of the policy period.

COUNT V – NO COVERAGE FOR ADULTERATED BOTANICALS

62. Gemini incorporates paragraphs 1 - 36.

63. The Specified Products Exclusion excludes coverage for "adulterated botanicals," whether a primary ingredient or in combination with other ingredients.

64. Accordingly, to the extent the DMAA Products contain an adulterated botanical (DMAA is allegedly derived from the geranium plant), Gemini has no defense or indemnity obligation to USP.

COUNT VI – THE SELF-INSURED RETENTIONS ARE NOT SATISFIED

65. Gemini incorporates paragraphs 1 - 36.

66. Satisfaction of the applicable self-insured retentions is a condition precedent to coverage under the Gemini excess policy.

67. Both the Gemini excess policy and the controlling underlying insurance have $250,000 self-insured retentions that apply on a "per claim" basis ($500,000 combined per claim for DMAA-related claims).

68. USP has provided no evidence that either self-insured retention is satisfied.

69. Accordingly, to the extent that USP does not establish that the self-insured retentions are satisfied, Gemini has no defense or indemnity obligation to USP.

RELIEF REQUESTED

WHEREFORE, Gemini respectfully requests that this Court:

a. Take jurisdiction and adjudicate the rights of the parties under the Policy;

b. Find that Gemini has no obligation to defend or indemnify USP in the DMAA Lawsuits; and

c. Award Gemini all costs it incurred to prosecute this action, as well as any other relief that this Court deems equitable, just, and proper.

Respectfully submitted,

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